REMARKS

The specification has been amended to conform with the reference numbers set forth in the drawings.

The Prior Art Rejection

Claims 25-32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Schatz (`333) in view of Sakura (`587). Preliminarily, it is believed that the Examiner has a typographical error in identifying the Schatz patent, and that the correct patent number is U.S. Patent No. 5,902,332 ("the `332 patent"), and it will be referred to accordingly herein as the `332 patent.

The Litigation

Applicants are informing the Examiner that the Schatz `332 patent has been asserted in patent litigation against the assignee of the pending application for alleged patent infringement of the ACS MULTI-LINK stent. The ACS MULTI-LINK stent is the commercial embodiment of the claimed invention. The assignee of the present invention, namely Advanced Cardiovascular Systems, Inc. ("ACS") has denied that its commercial device infringes the Schatz `332 patent and has alleged that the patent is invalid and not infringed. Applicants are attaching as Exhibit A, the Complaint in the referenced lawsuit and as Exhibit B, the Answer filed by ACS. Further, Applicants will make available to the Examiner any documents the Examiner deems necessary for the further prosecution of the application.

As to the substantive issues relating to the rejection under § 103, the Federal District Court for the District of Delaware has construed some of the claims of U.S. Patent No. 5,102,417 (Exhibit C). The Examiner is urged to review the drawing figures 1 through 6 of the `417 and the `332 patents and compare them to satisfy the Examiner that they are identical. More specifically,

Figs. 1A and 1B in each of the `417 and `332 patents relate to a tubular stent that is essentially rigid and unable to navigate tortuous coronary arteries as it is advanced into the coronaries for implantation. This single tubular stent was allegedly invented by a Dr. Palmaz, and it is fully disclosed in U.S. Patent No. 4,733,665. As documented in numerous depositions and documents produced by the parties in litigation, Dr. Palmaz and Dr. Schatz collaborated and allegedly invented a series of tubular stents connected together by flexible connector members as shown in the `417 patent. Although Dr. Schatz's name does not appear on the face of the `417 patent as a co-inventor, it was subsequently added. Dr. Schatz also alleges that he invented a single-strut connector member positioned between tubular stents in order to increase the flexibility of a stent as shown in Figure 8 of the `332 patent where the stent is advanced through a curved section of vessel. The Examiner also is encouraged to compare the specifications of the `417 and `332 patents for similarities relating to the description of grafts, prostheses, and tubular members. Many passages are identical. The foregoing background is important in making the substantive arguments over the prior art.

In litigation relating to the `417 patent, Judge Sue Robinson issued an Order on July17, 1998 denying the plaintiff, Cordis Corporation's Motion for preliminary injunction on various grounds. In the Order, the Court construed certain claim terms which may have a bearing on the Examiner's understanding of the `332 patent. The Order is attached hereto as Exhibit D. Specifically, Judge Robinson's Order, at page 16, defines an intraluminal graft to be functional, that is, neither the specification nor claim language required that the intraluminal grafts be of any particular length, however, such "grafts" must be functional, as would be expected in a method claim, such as claim 17 (Exhibit D, page 16). The `417 patent uses terms such as grafts, prostheses, and tubular members interchangeably to describe the stents that are connected together. Thus, her

Honor concluded that each of the connected grafts must be functional as a stent. Further, the Court also determined that "there is no requirement that a tubular member be any certain length, so long as it is long enough to contain more than one slot (Exhibit D, page 17). As the Examiner can see, each of the grafts, prostheses, and tubular members that are connected together each contain more than one slot which are the rectangular openings in each stent. The Examiner is encouraged to read all of Judge Robinson's Order.

The Examiner also is requested to consider and review a January 15, 1999 Memorandum Opinion (Markman Decision) (Exhibit E) in which Judge Robinson construed the claims of the `417 patent as well as the claims of U.S. Patent No. 4,739,762 (the `762 patent) and U.S. Patent No. 5,195,984 (the `984 patent). The `762 and the `984 patents are attached hereto as Exhibits F and G. The `984 patent to Schatz is the parent to the `332 Schatz patent which is the subject of the rejection made by the Examiner.

In the Markman Decision, Judge Robinson determined that these patents had a shared history and that the "language used in the multiple claims asserted is substantially similar and, the Court believes, should be construed consistently." (Exhibit E, p. 8.) Thus, by construing the `984 patent claims, the Judge can provide some insight to the Examiner as to how a Federal Court is construing claims and terminology as disclosed in the `332 patent. At page 14 of the Markman Decision, her Honor construed "tubular member" as a discreet structure that has the form of a tube, that is "a hollow elongated usually cylindrical body" wherein an "elongated" form is "notably long in comparison to its width." Further, her Honor determined that each tubular member must be elongated, i.e., "its length is greater than its width." (Exhibit E, p. 17.)

Response To Rejection

Thus, in view of Judge Robinson's Order concerning the `417 patent and the Markman Decision construing the `417, `762 and `984 patents, Applicants urge the Examiner to follow the District Court's claim construction relating to grafts, prostheses, and tubular members, which must be functional and be long enough to contain more than one slot. In other words, each of the grafts, prostheses or tubular members are in and of themselves a stent that is fully functional to hold open a body lumen and are elongated which means "its length is greater than the width."

The Examiner has characterized the Schatz `332 reference as having a plurality of cylindrical rings 71 aligned on a common axis. In view of the foregoing claim construction by the District Court, clearly the tubular member 71 is not considered a cylindrical ring by the Court. In fact, it is an elongated tubular member, each of which is connected to another elongated tubular member 71. The Court has determined that each tubular member 71 must be elongated, i.e., its length is greater than its width. (Exhibit E, p. 17.) The rings of the claimed invention clearly have a length that is shorter than the width (diameter) of the ring. Thus, the tubular member 71 referred to in the Schatz `332 patent cannot fairly be characterized as a cylindrical ring in view of the Court's specific claim construction.

With respect to the Sakura `587 patent, the projecting edges (12), identified by the Examiner, are fixed to the outer surface of the device and exist both in its unexpanded and expanded condition. In contrast, and as recited for example in claim 29, the projecting edges on Applicants' stent form when the stent is expanded from the first delivery diameter to the second expanded diameter. In other words, in the unexpanded condition, there are no projecting edges on any of the cylindrical rings or interconnecting elements. This is not the case with Sakura which always has

projecting edges in both the expanded and unexpanded condition. In Applicants' device, the projecting edges form on at least the cylindrical rings between the first end cylindrical ring and the second end cylindrical ring as the stent is being expanded from the first delivery diameter to the second delivery diameter. Thus, in view of the substantial differences in structure, it is respectfully urged that the claims of the present invention are patentably distinguishable over the cited prior art.

Double Patenting Rejection

Claims 25-32 have been provisionally rejected under the judicially created doctrine of double patenting over the claims of co-pending application Serial No. 09/055,582. Further, claims 25-32 also have been rejected under the judicially created doctrine of double patenting over the claims of U.S. Patent No. 5,514,154. Applicants will file a terminal disclaimer to obviate any double patenting rejection upon Notice of Allowability.

It is respectfully requested that the prior art rejections be withdrawn and that the claims are patentably distinguishable over the art. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of the application.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____

Thomas H. Majcher
Registration No. 31,119

JSN:jeb

10877 Wilshire Boulevard, Tenth Floor
Los Angeles, California 90024
(310) 824-5555